REMARKS

This Response addresses the Detailed Action dated August 27, 2002. As suggested, I have "deleted" and "cancelled" Claims 1-20, and "added" and, as requested, double-spaced Claims 21-40 above. As requested in the Interview Summary, I have confirmed that the "added" Claims are supported by specific passages from the originally filed specification.

An Introduction to My Invention

Unlike the first generation systems of Evans, Walker, and Bardy, my invention is a powerful, refined health care related records access system. My invention enables and executes access rules based on access parameters to provide sophisticated records management capabilities beyond the one-dimensional functionality discussed in the cited patents. As an example, with my invention, the records of a patient are selectively accessed in accordance with access parameters and access rules that consider the role of the person desiring access (e.g., medical health care provider versus billing personnel versus personal relation), the medical conditions of the patient, the amounts of money owed by the patient, etc. Based on these considerations, my invention selectively provides and denies access to the patient's records or, with even more desired precision, portions of the records.

Further, under my invention, access to a record or portion thereof surpasses the simplistic all-or-nothing discussion of the cited patents. Rather, my invention controls the extent to which access is provided by allowing or prohibiting certain transactions (e.g., create, display, modify, transmit). As another example, my invention enables an automatic alerting system based on satisfaction of complex threshold events as determined by analysis of records stored in an electronic database from possibly different sources over time and in connection with separate events. As yet another example, my invention allows a user of a records management system to organize a possible multitude of patient records based on selectable parameters and, to facilitate records management, to store the compilation for later use. These and other technology advances of my invention are recited in my claims and will be discussed more to some extent below.

The Evans Patent

Evans discloses an electronic medical record (EMR) system that allows healthcare providers to enter patient data immediately at the point of care from any geographical location. The EMR includes the capability to manage a wide variety of patient data formats, including patient data from external sources, such as laboratories, pharmacies, and legacy systems. Health care providers can acknowledge reviewing patient data, provide instructions (e.g., prescriptions), and approve recommendations for treatment by other providers. Further, records can be accessed by different providers, allowing real-time collaboration.

Column 15, line 22 mentions a system administrator having access to any patient data, whereas physicians get access to patient records within their specialty, whereas nurses and staff

may have access to records of patients within their immediate care. Column 15, line 34 talks about alternatively using the EMR in a different industries (e.g., legal, manufacturing, general administration).

Accordingly, Evans teaches a records system that merely provides first-generation all-or-nothing records access.

The Walker Patent ("Patient Care Delivery System")

In the Abstract, Walker discloses a method and apparatus for analyzing data from a patient telemetry device (remote monitoring equipment) and determining (i) whether physiological data of patient meets a threshold (an anomalous event has occurred), (ii) (if an anomalous event has occurred) whether a physician should be contacted, and (iii) if a physician should be contacted, selecting the physician to contact. Many physicians can be contacted in response to an anomalous event to ensure efficient response. At column 21, line 14, the Walker states "the invention provides a system that will alert physicians and/or patients when the patient's health takes a turn for the worse". At column 3, line 22 Walker also discusses defining a level of compensation to be provided in exchange for rendering of an expert diagnosis. Column 5, line 58 discusses patient monitoring based on updated thresholds, drug dispensing, GPS patient locator, remote defibrillator activation, emergency security services, medical records storage. In addition, starting at column 8, line 6, Walker discloses the kinds of data to be stored in tables.

At column 5, line 50, data from the patient telemetry device 120-1 is passed to the central server 200. At column 7, line 45, the central server 200 receives a continuous signal from each patient and determines if any predetermined patterns or data aberrations exist. If so, then there is a search for an expert physician and possible call to ambulance. The expert is paged and offered compensation. At column 7, line 63, if expert accepts, then data about patient and current pattern or data aberration is provided to expert.

See Figure 2. The processor 220 cooperates with support circuitry 240 and memory 230 to run various programs 1200 and use various databases 300-700 stored in storage device 250. The storage device 250 is used to store a reaction database 300 (Figure 3: for each alert, a system response to the alert at column 8, line 12), a physician database 400 (Figure 4: physician information at column 8, line 44), a criteria database 500 (Figures 5A-5B: objective or subjective criteria applied to a physician; e.g., preferred patients, insurance plans, hospitals, etc. at column 9, line 36), a patient database 600 (Figure 6: patient information and medical history at column 10, line 50), and an event database 700 (Figure 7: patient, physician, medical event, outcome, offers made, offers accepted at column 11, line 41). At box 1008 of Figure 10 at column 17, line 5, Walker discusses "historical data, current demand, insurance contracting, other contracts or other inducements" to help determine an appropriate offer to a physician to perform medical services.

Walker discusses alerts and notifications based on physiological information. At column 5, line 65, Walker states " the processor 124 may be programmed . . . to issue an alert to the central server 200 in the event of a patient heart rate exceeding an upper threshold level or dropping below a lower threshold level. Multiple parameter alarms may be programmed such that particular combinations of physiological parameter levels trigger specific alerts indicative of specific conditions".

Accordingly, Walker merely discusses analysis of physiological data for real-time response purposes, and thus fails to teach any complex ability to analyze aggregated data, both physiological and non-physiological data, from different sources over different times and events.

The Bardy Patent

Bardy discloses a system for determining a reference baseline of individual patient status for use in an automated collection and analysis patient care system. A set of collected measures is retrieved from a medical device adapted to be implanted in a patient. The measures set is processed into a set of reference measures. At column 3, line 5, the reference measures set is stored into the patient care record as data in a reference baseline indicating an initial patient status.

At column 10, line 7, Bardy teaches "The feed back module 55 provides automated feedback to the individual patient based, in part, on the patient status indicator 54." Bardy discusses four levels of automated feedback. At a first level, an interpretation of the patient status indicator 54 is provided ("The analysis module 53 monitors patient wellness and makes an automated determination in the form of a patient status indicator 54."). At a second level, a notification of potential medical concern based on the patient status indicator 54 is provided. At a third level, the notification of potential medical concern is forwarded to medical practitioners. At a fourth level, a set of reprogramming instructions based on the patient status indicator 54 could be transmitted directly to the implantable medical device.

Accordingly, Bardy merely teaches "feedback", which by definition is information from implantable medical devices back to a patient. Very cursorily, at column 10, line Bardy also mentions some transmission of a "notice" to medical practitioners but not personal relations of the patient.

CLAIMS 21 - 32

Claim 21 recites "determining access rules to selectively govern access to the component fields" of a patient's records. Claim 21 further recites "a first access parameter" and "a second access parameter" that allow selective access to, respectively, "a first predetermined amount of the component fields" and "a second predetermined amount of the component fields . . . not identical to the first predetermined amount". My invention is sophisticated records access system that applies access rules to provide varying levels of access to portions (i.e., "component fields") of a patient's records based on access parameters.

At column 15, line 22, Evans mentions a system administrator having access to any patient data, whereas physicians get access to patient records within their specialty, whereas nurses and staff may have access to records of patients within their immediate care. Unlike my invention, Evans teaches a primitive records system that provides indiscriminant all-or-nothing records access. For at least these reasons, Evans and the other patents singly or in combination fail to teach selective access to a portion of the patient's records based on various access parameters.

Claims 22-32 are patentable because they depend from patentable Claim 21. In addition, all of my inventions of Claims 22-32 are separately patentable in their own right. To not overburden you, I have abbreviated my discussion about their patentability.

Claim 22, dependent on Claim 21, recites "the providing access to the first predetermined amount of the component fields includes providing access to the first group of individuals, the first predetermined amount relating to a first medical condition of the patient" and "the providing access to the second predetermined amount of the component fields includes providing access to the second group of individuals, the second predetermined amount relating to a second medical condition of the patient". Claim 22 enables one group of people to access records about one medical condition, and enables another group of people to access records about another medical condition. Each of the cited patents, whether alone or in combination, does not cover the kind of sophisticated, discriminating access system of my invention.

Claim 23, dependent on Claim 21, recites "considering a role of a person desiring access" and a "login identifier associated with the role". My invention considers not the individual identity of a person seeking access but the role of that person, as indicated by the person's login identifier, in making a more sophisticated, rules-based determination about what records should be accessible. None of the patents teach this advance.

Claim 24, dependent on Claim 21, recites "considering a role of a person desiring access" and providing complete access for a "health care provider". My invention considers not the individual identity or special circumstances of a person seeking access but the role of that person – i.e., health care provider – in making a more sophisticated, rules-based determination about what records should be accessible. Evans and the other patents fail to teach any selective access based on a person's role.

Claim 25 and Claim 26 recite, respectively, providing "a fraction of all the component fields" when access is desired by "billing or accounting personnel" and "denying the billing or accounting personnel access to the patient welfare component fields". My invention streamlines access to financial records needed by accounting and billing information but also denies them unnecessary and intrusive access to records that are reflective of a patient's medical condition. Evans and the other patents fail to teach the customized approach of my invention.

Claim 27, dependent on Claim 21, recites "considering a role of a person desiring access" and providing partial access for a "personal relation who is not a medical care provider of the patient". My invention innovatively recognizes the need or desirability for personal relations of a patient to have some access to a patient's health care related records. Evans, and the other patents, fail to teach my advance of enabling selective access to records based on a person's role and, in particular, fail to teach the role of a personal relation who receives some access to records.

Claim 28, dependent on Claim 21, recites "providing access to the first group of individuals" when the "first predetermined amount [is] indicative of good health", and "providing access to the second group of individuals and denying access to the first group of individuals" when "the second predetermined amount [is] indicative of bad health". My invention allows both a first and second group of people to access records that indicate the patient is in good health. However, my invention selectively prohibits the first group of individuals to access records that indicate the patient is in bad health. With my invention, a patient could, for example, suppress records reflecting bad health to contain undesirable awareness or concern about the patient's poor condition. My invention allows an advanced screening capability that Evans and the other patents do not teach.

Claim 29, dependent on Claim 21, recites providing access for some people to some component fields "satisfying a first criterion about monetary amounts owed" and providing access for other people to other component fields "satisfying a second criterion about monetary amounts owed". Thus, my invention enables selective access to some component fields for a first group when one financial condition is met and selective access to other component fields for a second group when another financial condition is met. By way of illustration, one group of people (e.g., patient's personal relations) would be able to see, for example, patient component fields associated with patient visits that have been paid for in full while another group of people (e.g., patient's financial advisor) would be able to see patient component fields associated with patient visits for which the patient has not yet paid. None of the patents, including Evans, teach this multidimensional access system enabling varying access based on satisfaction of different financial conditions.

Claim 30, dependent on Claim 21, recites "associating with one of the component fields permitted transactions", "associating with the one component field unpermitted transactions", and "restricting manipulation . . . to only the permitted transactions". My invention enables a refined capability to uniquely prescribe permitted and unpermitted transactions for each component field of a record.

Evans and the other patents fail to teach my invention. At column 15, line 22, Evans mentions a system administrator having access to any patient data, whereas physicians get access to patient records within their specialty, whereas nurses and staff may have access to

records of patients within their immediate care. Basically, Evans states that, once a person has access to a patient, the person gets access to the patient's entire record. Accordingly, under Evans, a physician gets to see all medical records in her area and the janitor gets to see none. In contrast, my invention provides for selective access to records of one patient, not only with respect to what portions can be accessed but also what transactions are permissible. Why should an IT professional (e.g., email system administrator) get to see that a patient is suffering from HIV? Evans says the IT professional gets access to the HIV patient's records. Also, why should billing personnel get to know that a patient is suffering from breast cancer? Even if the billing personnel somehow should get access to a patient's breast cancer records, why should the billing personnel get to modify or transmit such sensitive records? And, what if the patient wants her husband to know how one of her medical conditions is progressing without letting her kids see her progress for that medical condition, while giving her kids access to other records regarding her other medical conditions? Evans and the rest of the patents are one-dimensional, and fail to teach my invention.

Claim 31, dependent on Claim 30, recites "considering a role of a person desiring access". My invention considers not the individual identity or special circumstances of a person seeking access but the role of that person in making a more sophisticated, rules-based determination about what transactions should be permitted or unpermitted. For example, my invention would enable a personal friend of the patient to display a component field regarding the patient's medical condition but, in view of the friend's lack of medical training, prevent the personal friend from modifying the information about the medical condition. Evans and the other patents fail to teach any selective access based on a person's role.

Claim 32, dependent on Claim 21, recites "allowing the patient to determine a portion of the access rules". My invention uniquely enables and accommodates patient preferences regarding access to the patient's records and thus allows for sophisticated access regimes that receive and execute a patient's control and commands. The patents, including Evans, are merely hard-coded, first-generation access systems that fail to enable programmability and scalability in records access systems based on dynamic patient preferences.

CLAIMS 33-37

Claim 33 recites "analyzing the records stored in the database", "defining a threshold event relating to both physiological and nonphysiological information about the patient", "programming the database . . . with the threshold event", and "automatically provide an electronic notification to an interested entity". With my invention, records are stored in a database for analysis. Thus, my invention enables an automatic notification system based on satisfaction of complex threshold events concerning both physiological and nonphysiological data as determined by analysis of records, stored in an electronic database, from possibly different sources over time and in connection with separate events.

In contrast, in the Abstract, Walker discloses a method and apparatus for analyzing data from a patient telemetry device. Walker discusses alerts and notifications based on physiological information. At column 5, line 65, Walker states " the processor 124 may be programmed . . . to issue an alert to the central server 200 in the event of a patient heart rate exceeding an upper threshold level or dropping below a lower threshold level. Multiple parameter alarms may be programmed such that particular combinations of physiological parameter levels trigger specific alerts indicative of specific conditions". This is the immediate medical response feature of Walker. Under Walker, physiological information alone defines a threshold which, in turn, prompts an alert.

Walker also discusses how the alert should be directed to a particular physician. At column 7, line 23, Walker discloses "a memory 230 to run various programs 1200 and use various databases 300-700 stored in storage device 250". The storage device 250 is used to store a reaction database 300 (Figure 3: for each alert, a system response to the alert at column 8, line 12), a physician database 400 (Figure 4: physician information at column 8, line 44), a criteria database 500 (Figures 5A-5B: objective or subjective criteria applied to a physician; e.g., preferred patients, insurance plans, hospitals, etc. at column 9, line 36), a patient database 600 (Figure 6: patient information and medical history at column 10, line 50), and an event database 700 (Figure 7: patient, physician, medical event, outcome, offers made, offers accepted at column 11, line 41). At box 1008 of Figure 10 at column 17, lines 5-52 (cited in Interview Summary), Walker discusses "historical data, current demand, insurance contracting, other contracts or other inducements" to help determine an appropriate offer to a physician to perform medical services. At column 16, lines 57-60 (cited in Interview Summary), new rounds of offers may be sent to physicians in certain circumstances. While nonphysiological information may influence how an alert is ultimately routed, the threshold event which initially triggers the alert in Walker is determined by physiological information only, unlike my invention.

For example, if a patient's immediate physiological data exhibits permanently declining health, Walker teaches, for example, a notification to a physician for treatment. In contrast, my invention would additionally store that information in a database along with other medical records of the patient. Assume that a complex threshold rule is defined that requires notification of the patient's accountant for additional payments if the patient health is in permanent decline and if the patient owes more than $200,000 to the health care provider. Walker cannot do this because it narrowly focuses on real-time physiological data only – my invention provides this capability. For at least these reasons, the combination of the other patents along with Walker also does not teach this.

Claims 34-37 are patentable because they depend from patentable Claim 33. In addition, all of my inventions of Claims 34-37 are separately patentable in their own right. To not overburden you, I have abbreviated my discussion about their patentability.

Claim 34, dependent on Claim 33, recites "records contain information received from various communication devices". The patents do not describe this.

Claim 35, dependent on Claim 33, recites "the threshold events relates to monetary amounts owed by the patient" and "the electronic notification includes a request to make payments to the health care provider after services are performed".

With regard to a cancelled claim, the Detailed Action (i.e., "(a)") states Walker discloses "data representing an amount of money due for a particular service provided by a physician" and cites various portions of Walker in support. However, I could not find the disclosure in any of the cited portions. The closest discussion in Walker about money-related topics seems to appear at column 3, line 22, where Walker merely discusses initially defining a level of compensation to be provided in exchange for rendering of an expert diagnosis well before any rendering of services.

In fact, Walker teaches away from my invention, and merely discloses physicians automatically receiving physiological information. At column 1, line 65, Walker teaches monitoring of data from a patient telemetry device. At column 3, lines 9-26, Walker teaches a monitored operating parameter which is a physiological parameter – this is the only possible kind of parameter that can be monitored in view of the data captured by the patient telemetry device. Walker discusses alerts and notifications based on physiological information. At column 5, line 65, Walker states " the processor 124 may be programmed . . . to issue an alert to the central server 200 in the event of a patient heart rate exceeding an upper threshold level or dropping below a lower threshold level. Multiple parameter alarms may be programmed such that particular combinations of physiological parameter levels trigger specific alerts indicative of specific conditions". Walker in combination with the other patents does not teach my advance at all.

Claim 36, dependent on Claim 35, recites "the interested entity is the patient". My invention enables automatic electronic notifications to a patient about money owed so that, for example, the patient can be automatically, electronically prompted to make payments.

At column 3, line 22, Walker discusses operating data provided to an "expert". The expert is to be provided compensation in exchange for rendering an "expert diagnosis". This teaches away from notifying a patient when she owes money because the patient can in no way be deemed to be an "expert, much less one that provides an "expert diagnosis" in exchange for compensation. At column 4, line 23 and column 5, line 58, Walker again teaches "physiological parameter" and "physiological information". At column 11, line 49, Walker teaches listing physicians to whom offers were made, not automatically contacting patients who owe money.

Furthermore, with respect to cancelled claims, the Detailed Action (i.e., "(d)") states that Evans provides an "effective means to access and share information between a healthcare provider and other entity such as a patient (Evan; col. 2 lines 5-20)". However, at column 2, lines 5-20, Evans teaches patient data at remote locations for analysis by healthcare providers.

"Moreover, the use of a patient's file by one health care provider can preclude its simultaneous use by another healthcare provider." Under circumstances involving the "transfer and maintenance of patient data in large enterprises", "healthcare providers have difficulty providing effective treatment for their patients". Evans addresses the problem of failed access by health care providers. Nothing in Evans, however, teaches automatic, electronic notification of a patient as does my invention.

Further, while Bardy teaches a "feedback process" of physiological information from an implantable medical device, Bardy fails to discuss notifications to a patient about monetary amounts owed.

Claim 37, dependent on Claim 33, recites "the interested entity is a personal relation of the patient" and "the electronic notification includes at least a portion of the record". My invention provides a scalable access system for family and friends of the patient to receive automatic, electronic notifications about a patient. Bardy teaches a continual "feedback process" of medical information from an implantable medical device, which by definition returns notices back to the patient, not to a personal relation of the patient. In particular, at column 10, line 7, Bardy states "automated feedback to the individual patient". At the third level, Bardy briefly mentions the forwarding of a notice to medical practitioners. Bardy fails to teach the transmission of records to personal relations.

CLAIMS 38-40

Claim 38 recites "selectively organizing . . . according to selectable parameters based . . . upon the particular types of patient data". My invention provides a freedom to dynamically organize patient records according to selectable parameters. With respect to cancelled claims, the Detailed Action cites Evans at column 16, line 54 to column 17, line 29, which mentions a patient data repository 102 having a patient locator 200, data manager 202, and data interface 204. See Figure 12 and related discussion at column 8, line 19 to column 9, line 37. The patient locator 200 generates a unique patient identifier (PID) for each patient. The data manager 202 uses the PID to store and retrieve patient records. The data interface 204 permits communication with external sources to obtain patient data and to transfer patient information (e.g., prescriptions) from the patient data repository 102 to external healthcare providers. Accordingly, Evans fails to teach my invention of allowing the organization of file histories based on selectable parameters.

Claims 39-40 are patentable because they depend from patentable Claim 38. In addition, all of my inventions of Claims 39-40 are separately patentable in their own right. To not overburden you, I have abbreviated my discussion about their patentability.

Claim 39, dependent on Claim 38, recites "compiling . . . into a file history that is storable in the electronic database for later access". My invention provides a performance driven enhancement to assemble and store a file history of organized records to eliminate the need to

repeat processing for compilations of identical organizing efforts. Nothing in the cited patents covers this streamlining advance.

Claim 40, dependent on Claim 38, recites "one of the selectable parameters concerns patient billing related data". My invention allows organization of records based on billing data so that a billing professional or patient interested in financial status could, for example, gain access to an array of all record portions that relate exclusively to billing data and suppress access to all other irrelevant data. None of the cited patents teach this filtering innovation.

LATE FEE

Because my response is apparently late, I have enclosed an extra $55 to pay for an additional month. The www.uspto.gov website indicates that the $55 is the appropriate amount for an "Extension for response within first month" with respect to CFR 1.17(a)(1) and Fee Code 1251/2251.

Please let me know if you need any more information for my patent. I can be reached at home at 650.573.3328 or on my cell phone 650.245.0480. Thank you for your help.

Very truly yours,

James W. Soong

DEPOSIT DATE

I certify that I deposited this response with the US Postal Service as first class mail with postage fully prepaid on 12/26/02.

Date: 12/26/02 Signature: